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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,162	BOSNES, MARIE	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/26/2010 & 3/17/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2010 has been entered.

Claim Status

2. This office action is in response to papers filed on February 22, 2010. Claims 1-25 are pending in this application. Claim 1 is amended. Claim amendments have been reviewed and entered. Applicant's arguments filed on February 22, 2010 have been fully considered and addressed following rejections. Claims 1-25 are under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 5-12, 15-20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubler et al (TIG, 1995, 11, 378-379) in view of Lubenow et al (USPN 6,723,510 issued Apr. 20, 2004).

Claim 1 is drawn to isolating nucleic acid and protein from each other in a sample using magnetic particles capable of binding to either nucleic acid or protein. Schubler et al teaches oligodT magnetic particles for isolating ribonucleic acid in a sequence independent manner and Lubenow et al teaches ion exchange magnetic particles for isolating protein by effecting a chromatographic interaction as discussed below.

Regarding claim 1, Schubler et al teaches a method of isolating nucleic acid and proteins from each other in a sample and the method comprising contacting the sample with a plurality particulate solid supports, wherein nucleic acid components in the sample (i.e., RNA) become bound to the solid support (pg. 378, column 2, paragraph 2). Schubler et al also teaches that solid support comprises oligo-dT to which polyA containing RNA binds (pg. 378, column 2, and paragraph 2) and is the preferred solid support for binding ribonucleic acids as defined in the instant claims 24 and 25. Schubler et al further teaches that the polyA RNA bound to oligo-dT comprises a plurality of distinct RNA populations (Fig. 1a), which encompasses nucleic acid components in the in the sample are bound to solid support in a sequence independent manner. Schubler et al also teaches that solid supports to which nucleic acids components are bound are in the form of magnetic particles (pg. 378, column 2, and paragraph 2).

Schubler et al further teaches that proteins from the same sample are concentrated by ultrafiltration column comprising a filter, i.e., solid support (Fig. 2, pg. 379, column 1, paragraph 3), thus teaching proteins are on a solid support. Schubler et al also teaches nucleic acids and proteins are isolated from each other in a sample (Figs. 1 and 2). Schubler et al do not teach binding of proteins to the solid support by effecting a chromatographic interaction and solid support is in the form of magnetic particles.

Regarding claim 3, Schubler et al teaches that RNA is bound to a solid support (pg. 378, column 2, and paragraph 2) but do not teach distinct supports for binding DNA and RNA (column 5, lines 51-59).

Regarding claim 5, Schubler et al teaches that the DNA, RNA and protein are isolated from the same sample (Fig. 1 and 2).

Regarding claim 6, Schubler et al teaches that the RNA is mRNA (Fig. 1a and pg. 378, column 2, and paragraph 2).

Regarding claim 7, Schubler et al teaches that the DNA is genomic (Fig. 1b, and pg. 378, column 2, and paragraph 3).

Regarding claim 8, Schubler et al teaches that the total DNA is isolated (pg. 378, column 2, and paragraph 3) and/or the total DNA is isolated (Example 13, column 32, lines 21-67 and column 33, and lines 1-16).

Regarding claim 9, Schubler et al teaches that the RNA and DNA components, i.e., total nucleic acid component are isolated (Figs. 1a and 1b and pg. 378, column 2, and paragraphs 2 and 3).

Regarding claim 10, Schubler et al teaches that the total protein component is isolated (Fig. 2 and pg. 379, column 1, and paragraph 2).

Regarding claim 11, Schubler et al teaches that the sample is a parasitic nematode or Arabidopsis sample (pg. 378, column 2, and paragraph 1), which is a biological or environmental sample.

Regarding claim 12, Schubler et al teaches that prior to contacting sample with solid supports, the sample is subjected to homogenization, grinding and a cell lysis in a buffer solution (pg. 378, column 2, and paragraph 2), which encompasses a preliminary treatment step to free the nucleic acid and/or protein components from structures or entities in which they may be contained (column 5, lines 30-54).

Regarding claim 15, Schubler et al teaches that the sample is subjected to cell lysis step prior to contacting with solid support (pg. 378, column 2, and paragraph 2).

Regarding claim 16, Schubler et al teaches that A. thaliana tissue sample comprising Photosystem II D2 proteins (i.e., cell surface proteins of cells within) are subjected to grinding procedure prior to the cell lysis step (pg. 378, column 2, paragraph 2), which encompasses an invitro modification procedure prior to the cell lysis step. The Photosystem II D2 proteins of Schubler et al are the cell surface proteins of cells within as defined by Oswald et al (See ref. 11 of Schubler et al).

Regarding claim 17, Schubler et al teaches that the same cell lysate is used for nucleic acid and protein isolation thus teaching that the sample is not divided at any stage of the method (pgs. 378 and 379).

Regarding claim 18, Schubler et al teaches sample is divided (i.e., transferring) after grinding, i.e., preliminary treatment step ((pg. 378, column 2, paragraph 2).

Regarding claim 19, Schubler et al teaches that the sample is processed sequentially (pgs. 378 and 379).

Regarding claim 20, Schubler et al teaches that RNA is isolated first, then DNA and then protein (pgs. 378 and 379), which meet the limitation of claim, because steps may be performed in any order.

Regarding claims 24 and 25, Schubler et al teaches that the RNA is isolated using oligo-dT capture probe (pg. 378, column 2 and paragraph 2).

As described above, Schubler et al do not teach binding of proteins to the magnetic particles by effecting a chromatographic interaction. However magnetic particles for protein isolation were known in the art at the time of the claimed invention was made as taught by Lubenow et al.

Lubenow et al teaches method for separation and isolation nucleic acids and proteins from a sample using magnetic particles (column 3lines 58-67). Like Schubler et al, Lubenow et al teaches oligodT magnetic particles for binding polyA RNA (column 5, lines 38-67 and column 6, lines 1-27). Lubenow et al further teaches magnetic particles for protein isolation comprises ion exchange resins, hydrophobic interactions resins or nickel-nitrilotriacetic acids (Example 1 and column 2, lines 15-37 and column 10, lines 15-42), which encompasses a chromatographic interactions as defined in the instant specification (USPGPUB, paragraph 0056).

Lubenow et al teaches distinct supports for binding DNA and RNA (column 5, lines 51-59, limitation of claim 3).

Combined teachings of Schubler et al and Lubenow et al provide solid supports to which nucleic acids components binds are distinct from solid supports to which proteins bind. Magnetic particles of Lubenow et al for protein isolation are deemed to work in the combined isolation of nucleic acids and proteins in the method of Schubler et al because lysis buffer of Schubler et al (pg. 378, column 2, paragraph 1) are compatible with that of Lubenow et al (column 4, lines 13-27).

Lubenow et al also teaches isolating molecules with the magnetic particles comprising affinity ligands improves the yield of molecules of interest, reproducibility of the isolation method and increases the signal to noise ratios of molecules of interest (column 5, lines 7-22).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the protein isolation method of Schubler et al with the magnetic solid supports for the protein isolation method of Lubenow et al with a reasonable expectation of success.

An artisan would have been motivated to modify the protein isolation method of Schubler et al with the expected benefit of having magnetic particles for protein isolation for improving the yield of protein molecules of interest and reproducibility of the protein isolation method and increasing the signal to noise ratios of protein molecules of interest as taught by Lubenow et al (column 5, lines 7-22).

5. Claims 1, 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubler et al (TIG, 1995, 11, 378-379) in view of Lubenow et al (USPN 6,723,510 issued Apr. 20, 2004) as applied to claim 1 as above and further in view of Ekenberg et al (USPN 6,218,531 issued Apr. 17, 2001).

Teachings of Schubler et al and Lubenow et al regarding claim 1 are described above in section 4.

Regarding claims 2 and 21, Schubler et al and Lubenow et al do not teach DNA and RNA are bound to the same solid support.

Regarding claim 22, Schubler et al teaches nucleic acid isolated by binding to a solid support in the presence of a detergent (pg. 378, column 2, and paragraph 2). Schubler and Lubenow et al do not teach DNA isolation by binding to a solid support in the presence of a detergent.

However, solid support for binding DNA and RNA was known in the art at the time of the claimed invention was made as taught by Ekenberg et al.

Ekenberg et al teaches a method for isolating nucleic acids wherein DNA and RNA are bound to the same solid support (i.e., silica matrix) in the presence of a detergent (column 8, lines 24-30, column 10, lines 32-34) and further teaches that the silica matrix is in the form of magnetic beads (column 5, lines 38-41). Ekenberg et al also teaches the magnetic beads coated with silica matrix are useful for isolating nucleic acids from number of different biological sources and diagnosing diseases, identifying pathogens, testing foods and a variety of other molecular biological applications (column 11, lines 55-67 and column 17, lines 6-12).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the nucleic acid isolation method of Schubler et al with the magnetic solid supports for isolating DNA and RNA of Ekenberg et al with a reasonable expectation of success.

An artisan would have been motivated to modify the nucleic acid isolation method of Schubler et al with the expected benefit of having magnetic beads coated with silica matrix, which are useful for isolating nucleic acids from number of different biological sources and diagnosing diseases, identifying pathogens, testing foods and a variety of other molecular biological applications as taught by Ekenberg et al (column 11, lines 55-67 and column 17, lines 6-12).

6. Claims 1, 3-4, 13-14, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubler et al (TIG, 1995, 11, 378-379) in view of Lubenow et al (USPN 6,723,510 issued Apr. 20, 2004) as applied to claim 1 as above and further in view of Safarik et al (Allen et al, Editors, Academic press, 2000, pgs. 2163-2170).

Teachings of Schubler et al and Lubenow et al regarding claim 1 are described above in section 4.

Regarding claims 3 and 4, Schubler et al teaches that RNA is bound to a solid support (pg. 378, column 2, and paragraph 2). Lubenow et al teaches distinct supports for binding DNA and RNA (column 5, lines 51-59). Schubler et al and Lubenow et al do not teach binding DNA and RNA to different solid supports in separate steps.

Regarding claims 13 and 14, Schubler et al and Lubenow et al do not teach cell isolation method.

Regarding claims 21 and 22, Schubler et al and Lubenow et al do not teach the solid support for DNA isolation comprises carboxyl groups and DNA binding to a solid support occurs concomitantly.

However, method steps of claims, 4, 13-14, 21 and 22 were known in the art at the time of the claimed invention was made as taught by Safarik et al.

Safarik et al teaches DNA and RNA is bound to different solid supports in a separate steps and further teaches using magnetic particles with carboxyl surface groups for DNA isolation (Table 2 and pg. 2166, basic principles of Magnetic affinity separations section). Safarik et al also teaches and further teaches isolation of cells by immuno-magnetic separations (pg. 2167, column 2, and paragraph 2). Safarik et al also teaches cell lysis and nucleic acid binding to a solid support occurs concomitantly (pg. 2164, column 1 and paragraph 1).

Safarik et al further teaches magnetic affinity separation method allows isolation of both low and high molecular weight substances of various origins directly from crude samples thus reducing the number of purification steps thereby facilitating the on site environmental contaminants and near patient analysis of various disease markers (pg. 2169, column 2, paragraphs 2 and 3).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the claimed invention was made to modify the magnetic support for nucleic

acid isolation method of Schubler et al with the magnetic solid supports with a variety of affinity reagents of Safarik et al with a reasonable expectation of success.

An artisan would have been motivated to modify the magnetic support nucleic acid isolation method of Schubler et al with the expected benefit of having a variety of magnetic beads coated, which are useful for isolating both low and high molecular weight substances of various origins directly from crude samples thus reducing the number of purification steps thereby facilitating the on site environmental contaminants and near patient analysis of various disease markers as taught by Safarik et al (pg. 2169, column 2, paragraphs 2 and 3).

Instantly claimed method steps comprise the use of distinct magnetic particles for isolating nucleic acids and proteins. As described above, magnetic particles with different affinity ligands as well as method steps are taught by Schubler et al, Lubenow et al, Ekenberg et al and Safarik et al. Therefore claimed method steps are obvious over the combination of cited prior arts, barring any secondary considerations.

Response to remarks from Applicants

Claim Rejections under 35 U.S.C. § 103(a)

7. Applicant's arguments with respect to claims 1-25 filed on February 22, 2010 as being unpatentable over Laugharn et al in view of Smith et al have been fully considered (Remarks, pgs. 5-8). These arguments are moot in view of claim amendments, withdrawn rejections and new grounds of rejections as set forth in this office action necessitated by claim amendments.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Stephen Kapushoc/

Primary Examiner, Art Unit 1634